K000742

MAR 2 9 2000

510(k) Summary of Safety and Effectiveness

SYNTHES (U.S.A.)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700
Contact: Jonathan Gilbert
3/23/00

DEVICE: Synthes Spine Anterior CSLP System [formerly known as: Synthes Spine Small Stature Anterior Cervical Vertebrae Plate System (as part of Synthes Anterior Cervical Vertebrae Plate System, K945700),10/27/97]

DESCRIPTION
The Synthes Anterior Cervical Vertebrae Plate System including the Small Stature Anterior Cervical Vertebrae Plate System consists of plates with expansionhead screws and locking screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2-C7). The implants of these systems are manufactured from titanium.

INDICATIONS
The Small Stature Anterior Cervical Vertebrae Plate System (as part of the Anterior Cervical Vertebrae System) is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications:

Spondylolisthesis
Fracture
Spinal stenosis
Tumor

CLASSIFICATION:
The classification of the subject device is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3060: Spinal intervertebral body fixation orthosis. The product code is KWQ. The Panel code is 87

BASIS OF SUBSTANTIAL EQUIVALENCE:
The components of the Synthes Spine Anterior CSLP system are similar to the components of previously cleared spinal systems. Mechanical testing shows the biomechanical performance of the subject device to be similar to the performance of previously cleared spinal systems with similar indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2000

Mr. Jonathan Gilbert
Senior Regulatory Affairs Associate
Synthes Spine
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K000742
Trade Name: Synthes Anterior CSLP System
Regulatory Class: II
Product Code: KWQ
Dated: March 6, 2000
Received: March 7, 2000

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R Lechner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): NA K000742

Device Name: **Synthes Anterior CSLP System**

The **Synthes Anterior CSLP System** is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications:

1. Spondylolisthesis
2. Fracture
3. Spinal stenosis
4. Tumor.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____(Per 21 CFR 801.109)

Donna R. Jochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000742